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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT) ..

(51) International Patent Classification 6 : A61B 17/74		A1	(11) International Publication Number: WO 98/30164 (43) International Publication Date: 16 July 1998 (16.07.98)
(21) International Application Number: PCT/EP97/06863 (22) International Filing Date: 9 December 1997 (09.12.97) (30) Priority Data: 08/782,231 13 January 1997 (13.01.97) US		(81) Designated States: AU, CA, CN, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
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<p>(54) Title: HELICAL OSTEOSYNTHETIC IMPLANT</p> <p>(57) Abstract</p> <p>An osteosynthetic implant for setting a broken bone (29). The implant comprises a nail (8) having a plurality of helically twisted blades (10, 12) that share a common helical axis. At least two of the blades (10, 12) define an angle (17) of less than 180° in a plane perpendicular to the helical axis. In a preferred embodiment, one pair of the blades (12) of the nail (8) is tapered towards its proximal portion and another pair of the blades (10) has a uniform thickness. The blades are twisted by at least about 30°. A cannulation (24) runs through the center of the nail (8) to receive a guide wire. The nail (8) is slidably engageable to a securing member (26, 40) that is securable to an elongated portion (28) of the bone (29), such as a side plate (26) or an intramedullary nail (40). In a preferred implantation orientation, the proximate portion of the tapered blades (12) is parallel to the elongated portion (28) of the bone (29), and a proximate portion of the uniform blades (10) is perpendicular thereto.</p>			

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HELICAL OSTEOSYNTHETIC IMPLANT

The invention relates to an implant for setting a broken bone according to the preamble of claim 1 and a nail according to the preamble of claim 19. It refers in particular to an implant for osteosynthesis of stable and unstable fractures of the neck and intertrochanteric region of the femur.

The elderly population experiences a high incidence of femoral fractures, commonly in the femoral neck and intertrochanteric regions. These fractures are normally treated by inserting a nail or hip screw from the side of the femur, through the neck, and into the femoral head. The nail or screw is then fixed to a side plate, that is fastened to the outside of the femur shaft, or to an intramedullary nail, that is inserted through the femur shaft. Both the side plate and the intramedullary nail may be secured to the femur shaft with bone screws.

A high incidence of death, between 10% to 25%, is associated with this type of hip fractures due to the injury itself or related complications. Frequent complications may arise when two or more bone fragments are forced towards each other when

the patient supports his or her weight on the healing bone. For example, an sharp implanted nail or hip screw may cut through and penetrate the femoral head or neck; or a nail, hip screw, side plate, or intramedullary nail may bend or break under load where the contact between bone fragments is insufficient for the bone itself to carry the patient's weight.

Collapsible implants have been developed to maximize bone to bone contact by permitting bone fragments to migrate towards one another. Examples in the prior art include the Richards-type compression hip-screw and the Kenn-type nail. Richards screws comprise a long, smooth shaft and external threads at the tip. Kenn nails comprise a wide, tri-flanged tip at the end of a smooth shaft. In both examples, the nail or screw implanted through the neck of the femur is allowed to slide back through the side plate or intramedullary nail as the bone fragments move together under a load.

On the other hand, these known implants are laterally stiff. Their sharp ends may cut sideways through the cancellous tissue of a femoral head after implantation and migrate within the bone, either piercing the surface of the femur or simply no longer retaining proper alignment of bone fragments. To resolve this problem, single, helical blades were developed, such as the SPIRAL BLADE brand, currently sold by Synthes, Paoli, PA, and such as disclosed in U.S. Patent Nos. 5,300,074 and 4,978,349. These blades are twisted about 90° along their length and have a substantially uniform width. When implanted

into the neck and head of a femur, the distal end of the blade lies in parallel with the femur shaft, and the proximal end lies perpendicularly to the shaft. In this position, the load on the head acts on relatively flexible, large, flat surface, reducing the pressure on the cancellous tissue and diminishing the tendency of the implant to further cut through the bone once implanted. The distal end, being aligned with the femoral shaft, provides a higher bending stiffness than the tip to sufficiently support the blade. Also, unlike previous nails and screws, these blades require little or no material removal in the femoral head, prior to implantation, where the amount of bone is critical.

These single, helical blades, however, are fairly compliant in the transverse direction, towards the fore and aft of the patient's body, because of the vertical positioning of the distal end of the blade. Moreover, the blades provide little resistance to cutting through the cancellous bone like a knife in directions aligned with the width of the blade at any station along its length. A need exists, therefore, to provide improved osteosynthetic implants which do not have a tendency to cause such cutting.

The invention as claimed aims at solving the above described problems.

The present invention solves these problems by providing an implant as defined in claim 1 and a nail as defined in claim 19.

The invention relates to a dynamic osteosynthetic-implant that minimizes the tendency to cut through the cancellous bone tissue after implantation and provides the required stiffness to maintain the relative orientation of the bone fragments. One implant according to the invention includes a plurality of helically twisted blades fixed to one another along a common helical axis. At least two of the blades define an angle of less than 180° in a plane disposed perpendicularly to the helical axis. The blades are preferably slidably engageable to a first member, such as a side plate or an intramedullary nail, that is itself engageable to the shaft of a femur. These blades provide the implant with a relatively flexible, large area, proximal end, but which gradually becomes stiffer towards its distal portion for additional support.

In a preferred embodiment, two perpendicular pairs of oppositely oriented blades are helically twisted by at least about 30° . One pair of blades tapers towards its distal end; the other pair has substantially uniform widths. In a preferred implanted orientation, the distal ends of the uniform blades are oriented in parallel to the femoral shaft, while the distal ends of the tapered blades are oriented perpendicularly to the shaft. The respective proximal ends are oriented at about 90° of helical twist to their distal ends. As a result, the proximal end of the implant provides a large surface normal to the principal downward load on the head of the femur and is more compliant than the distal portion of the implant, with the distal portion having increased bending stiffness in all

directions. Moreover, the angle formed between any two adjacent blades, together with the portions of the blades normal to a shearing load on the bone, resist the tendency of the implant to cut out through the bone under such a load.

In the drawings:

FIG. 1 is a perspective view of a preferred embodiment of an implant according to the invention;

FIG. 2 shows a proximal view of an implant according to the invention;

FIG. 3 is cross-sectional side-view of an implant according to the invention implanted in a femur in conjunction with a side plate;

FIG. 4 illustrates a cross-sectional side-view of an implant according to the invention implanted in a femur in conjunction with an intramedullary nail;

FIG. 5 is a partial cross-section of a perspective of an alternative embodiment of the implant; and

FIG. 6 is a distal view of the embodiment shown in FIG. 5.

Referring to FIG. 1, an osteosynthetic nail 8 comprises a plurality of helically twisted blades 10 and 12 that are fixed to a proximal portion 14 of a shaft 16. In this description of the preferred embodiments, the terms distal and proximal are defined in relation to a surgeon implanting the device. Thus, a proximal portion of an element is preferably located closer to the central part of the body than its distal portion. The shaft 16 is coaxial with the common helical axis of the blades 10 and 12. The blades 10 and 12 are substantially flat and may have sharp proximal ends. Their helical twist is at least about 30°, preferably from about 45 to 120° and most preferably about 90°. The helical rate of twist is such that nail 8 may be driven into a femur from the distal end of the nail 8. After implantation, this twist also inhibits nail 8 from sliding forwards or backwards along its helical axis with respect to the femoral head.

The preferred embodiment comprises a pair of uniform blades 10 disposed on opposite sides of the helical axis and exhibiting a substantially uniform width, and a tapered pair of blades 12 disposed on opposite sides of the helical axis and substantially at right angles to the uniform blades 10. The angle 17 defined between at least two adjacent blades at any station along the helix, however, may be any angle of less than 180°. Preferably, this angle is between 30 and 150°, and more preferably between 60 and 120°. The most preferable angle when four blades are used is 90°. The tapered blades 12 are widest at their distal ends 18 and taper down, in the direction

of their proximal ends 20, until they lie flush with the outer surface of the proximal portion 14 of the shaft 16. Only one of the two proximal ends 20 of the blades 12 is visible in FIG. 1. From this vantage, the other is hidden behind the shaft 16.

A cannulation 24 extends along the inner length of shaft 16. The cannulation 24 is sized to permit the insertion of a guide wire (not shown) to aid in the alignment of the nail during the implantation procedure as is commonly known in the art.

FIG. 2 is a view from the proximal end of the nail which illustrates the helical shape of blades 10 and 12 and the taper of blades 12. It also shows the angle 17 formed between the blades 10 and 12. From this view, the distal ends 18 of the tapered blades 12 are directly behind the proximal tips of the uniform blades 10 and are thus hidden from view.

In FIG. 3, an embodiment that employs a side plate 26 is shown in a preferred implantation orientation. Side plate 26 is aligned with the shaft 28 of femur 29 and is securable to the outside thereof with fasteners 30, as shown in FIG. 3. A portion of the side plate 26, in one embodiment, may slide vertically with respect to fasteners 30 to allow for vertical compression of the bone fragments. The proximal portion 22 of shaft 16 is telescopically slideable within a cylindrical sleeve 32 that is fixed to the side plate 26 at an angle 33 that will be generally between 90° and 150°, but that may be selected according to the anatomy of the patient.

Alternatively, the side plate may be configured and dimensioned as a fixed plate that does not vertically move with respect to the fasteners. The length, width and other dimensions of either the fixed or slidable plate can be selected by one of ordinary skill in the art.

The implantation procedure for fixation nails is also well known in the art and can be applied with the present invention. In the preferred implantation orientation, sleeve 32 penetrates the side of the femur 29 towards the femur neck 34 and head 36. The distal portion 22 of shaft 16 in this embodiment has a larger outer diameter than does the proximal portion 14. This distal portion 22 is slidably engaged within sleeve 32 such that the distal ends of blades 10 and 12 are separated from the proximal end 38 of the sleeve. This separation enables the nail 8 to slide back into the sleeve 32 as the femur head 36 is compressed distally in the direction of the helical axis. This prevents the blades 10 and 12 from further cutting the head 36 after implantation.

The nail 8 is implanted inside the neck 34 and head 36 of the femur 29. The distal portions of the uniform blades 10 are oriented in parallel to the shaft 28 of the femur, while the distal portions 18 of the tapered blades 12 are perpendicular to the femur shaft 28. At their proximal ends, uniform blades 10 are perpendicular to the femur shaft while tapered blades 12 and proximal ends 20 are parallel to the femur shaft 28.

In this orientation, the wide proximal portions of the uniform blades 10 provides a large surface normal to the principal downward load imposed on the femoral head 36 when the patient stands and ambulates. This reduces the pressure on the cancellous tissue within the femur 29 and resists the tendency to cut through the bone cortex. The distal portions of the uniform blades 10, aligned with the principal load, increase the bending stiffness of the shaft 16 resisting that load, and efficiently transfer the load to the side plate 26. The taper in the tapered blades 12 affords additional stiffness in their distal portions 18, where blades 12 have a larger width, but retains the compliancy of the nail 8 at the tapered proximal ends 20. In this manner, the proximal part of the nail 8 may flex, rather than carve through, or crush, the bone tissue. In addition, the extra surface area furnished by tapered blades 12 also counter any propensity of the blades 10 and 12 to migrate laterally relative through the bone 29. Moreover, if the nail 8 is forced laterally into the bone tissue, the tissue will be driven into the angles formed between adjacent blades 10 and 12, further resisting nail 8 migration. Preferably, the outer diameter of sleeve 32 is about the size of the widest portion of nail 8 so that nail 8 may fit easily through a hole drilled for insertion of the sleeve 32, making it easier to achieve the above orientation.

An alternative embodiment is shown in FIG. 4. This embodiment utilizes an intramedullary nail 40 implanted in the femoral shaft 28. As in the first embodiment described, the nail 6 may slide telescopically within a channel 42 inside the intramedullary nail 40. The channel 42 defines an angle 44 with the length of the intramedullary nail 40 of generally between 90° and 150°, which may be chosen according to shape of the femur.

During implantation, the intramedullary nail 40 is inserted into the bone first. The nail 8 is then implanted through the side of the femur 29 through a hole drilled merely up to the depth of the side surface of the intramedullary nail 40. Helical grooves 46 extend radially from channel 42 and are shaped to receive blades 10 and 12. As the nail 8 is hammered into the bone, as commonly done by persons skilled in the art, blades 10 and 12 slide through grooves 46.

The preferred implantation orientation resembles that of the side-plate embodiment. The nail 8 is positioned in the same relationship to the femur 29 and shares the same advantages.

In another embodiment, with which either a side plate or an intramedullary nail may be employed, the distal end of the nail 8 defines a hexagonal cavity 48 concentric with the proximal base of the shaft 16 and the cannulation 24. This cavity 48 is shaped to receive the tip of an instrument, normally used in the art, designed to ease rotational orientation of the nail

during implantation. The cavity 48 may be shaped differently depending on the instrument used. For, example, instead of a central cavity, the distal base and sides of shaft 16 may have indentations or raised portions to fit the instrument.

The length and proportions of the elements of the invention may be selected by the surgeon according to the anatomy of the patient. Examples of selectable dimensions include the length of nails 8 and sizes of side plate 26 or intramedullary nail 40. Also, other embodiments may contain a different number of blades, if desired.

It will be appreciated that those skilled in the art may devise numerous modifications and embodiments. It is intended that the following claims cover all such modifications and embodiments that fall within the true spirit and scope of the present invention.

CLAIMS

1. Implant for setting a broken bone (29) comprising a nail (8) having a plurality of helically twisted blades (10,12) for implantation in a bone fragment, said blades (10,12) being fixed to one another and aligned along a common helical axis, at least two of said blades defining an angle of less than 180° in a plane disposed perpendicularly to said helical axis.
2. Implant according to claim 1 further comprising a securing member (26,40) being securable to an elongate portion (28) of the bone (29), said blades (10,12) being engageable to said securing member (26,40).
3. Implant according to claim 1 or 2, characterized in that said blades (10,12) are substantially flat and said at least two blades (10,12) define an angle (17) of between 30° and 150°.
4. Implant according to one of the claims 1 to 3, characterized in that said helical blades (10,12) have a rate of helical twist such that they can be driven into a bone (29), and said at least two blades (10,12) define an angle (17) of between 60° and 120°.
5. Implant according to one of the claims 1 to 4, characterized in that said helical blades (10,12) are twisted by at least about 30° along said helical axis.

6. Implant according to one of the claims 1 to 5, characterized in that said helical blades (10,12) comprise at least one tapered blade (12) having proximal and distal widths, said distal width being disposed toward said securing member (26,40) and being greater than said proximal width.
7. Implant according to one of the claims 1 to 6, characterized in that said at least one tapered blade (12) is twisted by about 45° to 120° along said helical axis.
8. Implant according to one of the claims 1 to 7, characterized in that said tapered blade (12) is twisted by about 90° and said nail (8) may be implanted such that the distal width of said tapered blade (12) is parallel to the elongate portion (28) of the bone (29).
9. Implant according to one of the claims 1 to 8, characterized in that the blades (10,12) are movably engaged to the securing member (26,40).
10. Implant according to one of the claims 1 to 9, characterized in that the blades (10,12) are slidably engaged to the securing member (26,40) in a direction parallel to said helical axis permitting compression of bone fragments.

11. Implant according to one of the claims 1 to 10, characterized in that it further comprises a telescoping portion (22) of the nail (8) which is telescopically engageable to the securing member (26).

12. Implant according to one of the claims 1 to 11, characterized in that said securing member (26,40) comprises a sleeve (32) for receiving said nail (8) preferably a telescoping portion (22) of said nail (8).

13. Implant according to claim 12, characterized in that said sleeve (32) comprises an outer sleeve diameter; and said helical blades (10,12) define a helical diameter which is at most about as large as said outer sleeve diameter.

14. Implant according to claim 12 or 13, characterized in that said securing member (26,40) defines helical grooves (46) extending from an inside portion of the sleeve (32) and being aligned therewith, said helical blades (10,12) being slideable within said grooves (32).

15. Implant according to one of the claims 1 to 14, characterized in that nail (8) further comprises a hollow shaft (16) for receiving a guide wire, said hollow shaft (16) extending coaxially with said helical axis.

16. Implant according to one of the claims 1 to 15, characterized in that said securing member (26) is securable to an outside portion (28) of the elongate portion of the bone (29).

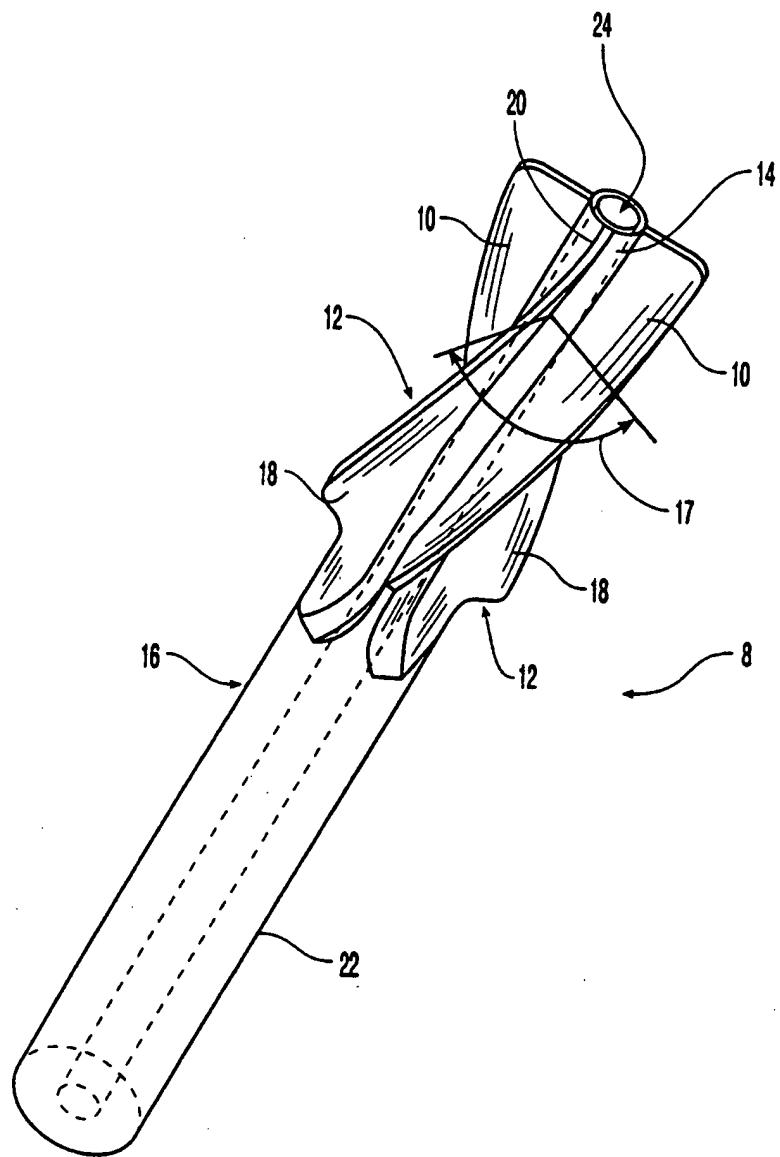
17. Implant according to one of the claims 1 to 16, characterized in that said securing member (40) comprises an intramedullary nail for insertion within the elongate portion (28) of the bone (29), in a direction substantially parallel thereto.

18. Implant according to one of the claims 1 to 17, characterized in that said securing member (26,40) and said helical axis define an angle of between about 90° and 150°.

19. A nail (8) for setting a broken bone (29), the nail comprising:

- A) a shaft (16) defining a helical axis;
- B) a uniform pair of blades (10) disposed on the shaft (16);
- C) a tapered pair of blades (12) disposed on the shaft (16) in a manner such that each tapered blade (12) is positioned between the uniform pair of blades (10), said tapered blades (12) having a greatest width at a distal portion and a smallest width at a proximal portion, said uniform and tapered blades (10,12) having a total helical twist of at least about 30° around the helical axis; and

D) wherein said nail (8) is drivable into the bone (29) and a distal portion of the nail (16) is slidably engageable to a securing member (26,40), said securing member (26,40) being securable to an elongate portion (28) of the bone (29).

**FIG. 1**

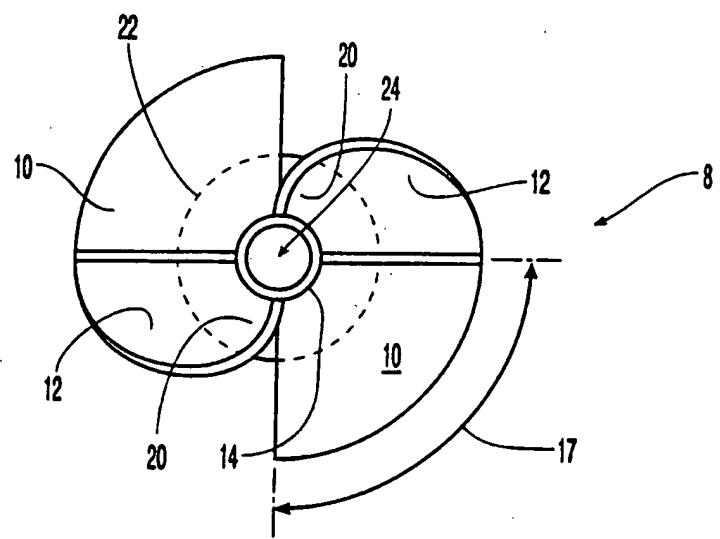
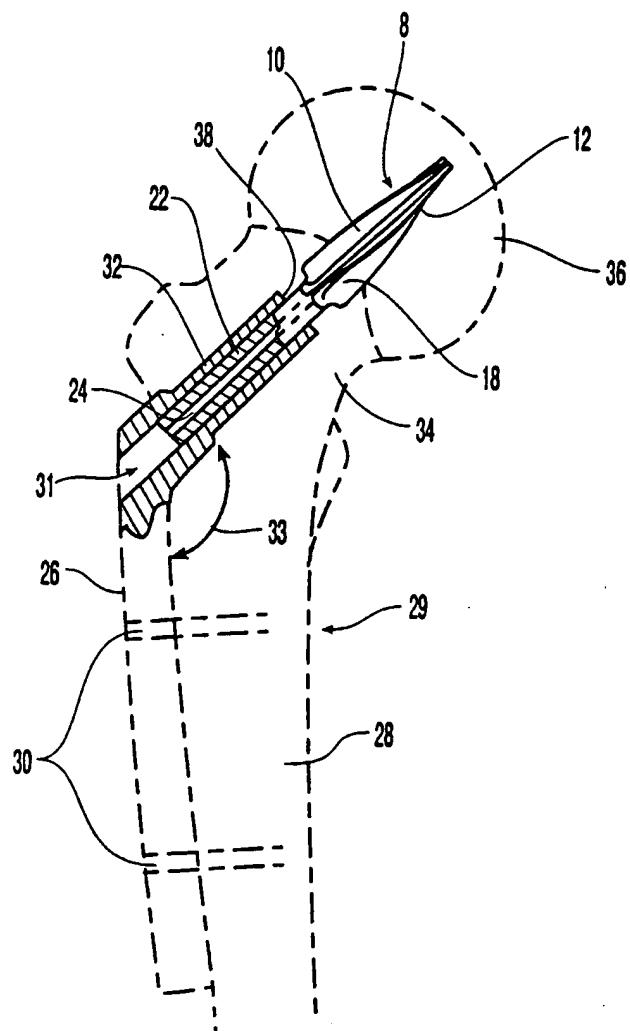
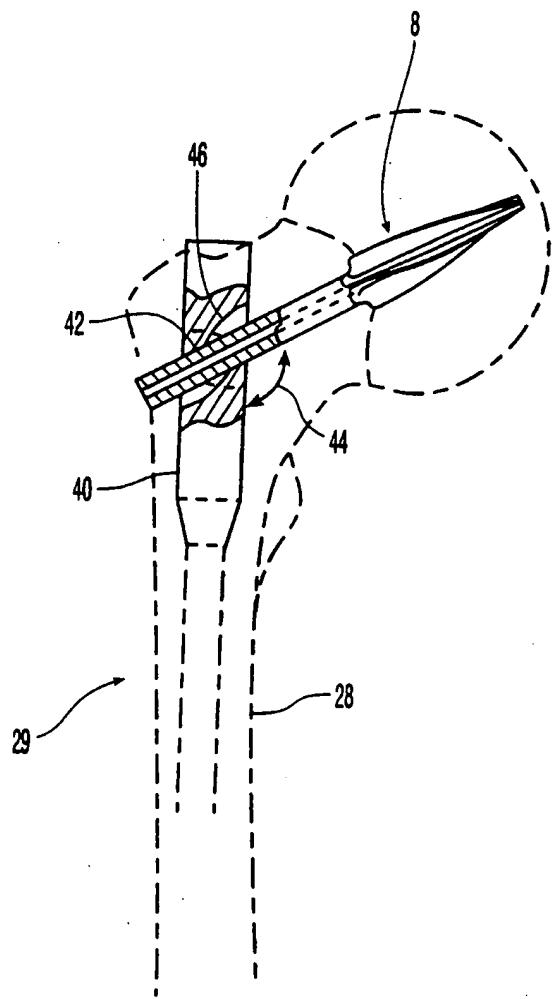
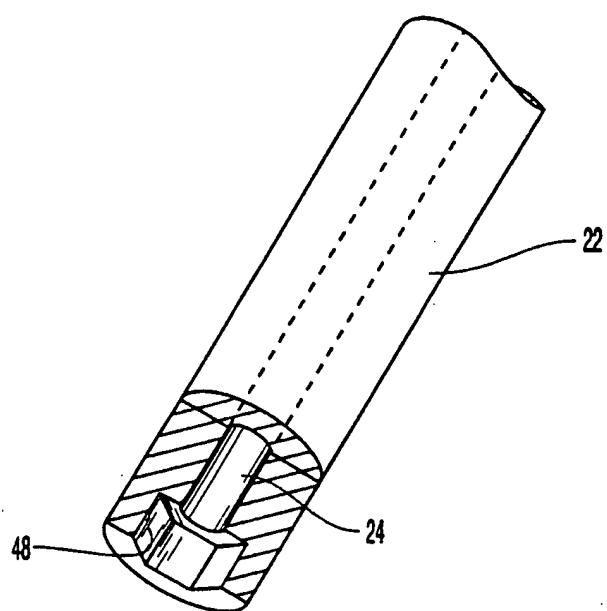
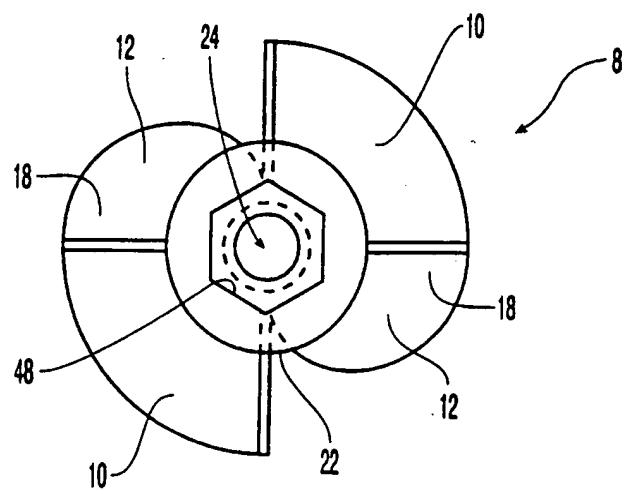


FIG. 2

**FIG. 3**

**FIG. 4**

**FIG. 5****FIG. 6**

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 97/06863

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/74

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Section P0, Week 8440 Derwent Publications Ltd., London, GB; Class P31, AN 84-248502 XP002064244 & SU 1 071 298 A (V.V.KOPTYUKH), 7 February 1984 Y see abstract; figure 1	1,3-5
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A	---	-/-

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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X	DATABASE WPI Section PQ, Week 8815 Derwent Publications Ltd., London, GB; Class P31, AN 88-104222 XP002064245 & SU 1 337 074 A (V.V.KOPTYUKH), 15 September 1987 see abstract; figure	1,4,5,15
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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